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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 19

Application Number: 09/681,303

Filing Date: 10/30/2003

Appellant(s): Liprie

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GROUP 3600

H. M. Bedingfield

For Appellant

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EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/30/2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

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The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that the claims stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,282,781	LIPRIE	2-1994
5,454,794	NARCISO ET AL	10-1995
5,230,348	ISHIBE ET AL	7-1993
5,163,896	SUTHANTHIRAN ET AL	11-1992
5,395,300	LIPRIE	3-1995

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Statements about intended uses, capabilities, or structures which may result upon the performance of future acts (i.e., when bent), are not positive structural limitations and in this sense fail to comply with the requirements of the statute in failing to distinctly claim the actual invention. Note In re Collier, 158 USPQ 266.

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B. Claims 1-6, 9-15, 17-25 and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Liprie (5,282,781).

Liprie ('781) discloses applicant's inventive concept. A source wire for localized radiation treatment of tumors comprising: a flexible (see column 5, lines 60+) elongated *stainless steel* (12) tube/housing an outer diameter of 0.018 inches, the tube/housing further comprising a distal end (15) and proximal end (14); a flexible *stainless steel* backbone wire (17) with a distal and proximal end completely disposed within the tube/housing; an iridium-192 radiation source (25) provided in the tube/housing adjacent the proximal end of the flexible backbone wire, the source being two centimeters in length; and a *stainless steel* plug (27) which seals the proximal end of the tube/housing.

Liprie ('781) further discloses that the flexible elongated tube/housing can be constructed of other materials such as titanium or *tantalum* and that the outer surface of the flexible elongated tube/housing is coated with a non-oxidizing agent (i.e., gold). Liprie ('781) also discloses a crimping method of affixing the flexible elongated tube/housing to the backbone wire. Additionally, Liprie ('781) discloses that it is well known within the art to encapsulate the radiation source in a material such as stainless steel (see column 4, lines 10+) to prevent the flaking of the radiation source and to provide such sources with radiopaque markers so as to observe the source with fluoroscopy (see column 16, lines 64+). Also note Liprie ('781) further discloses (see figure 1 and column 9, lines 19+) the inner surface of the proximal end of the housing tube exhibiting a tapered funnel shape for ease of loading the radioactive source within said housing tube. Applicant is not claiming the final product/version of the source wire to be funnel shaped.

Note in regard to the final product/version of the source wire Liprie ('781) appears to provide an alternative plug shape (i.e., other than rounded or bullet shaped)(see column 12, lines 21+). Here after the

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final draw down thin portions of the distal end 15 of the composite source wire 10 are molecularly removed by conventional electroetching to round off or taper the tip. The purpose of the rounded or tapered end of the composite source wire is to ease advancement of the source wire by the loader 35 through an implanted catheter to the tumor site for in vivo localized radiation treatment of the tumor. It appears that such an alternative reads on the embodiment of figure 3.

While patent drawings are not drawn to scale, relationships clearly shown in the drawings of a reference patent cannot be disregarded in determining the patentability of claims. See In re Mraz, 59 CCPA 866, 455 F.2d 1069, 173 USPQ 25 (1972).

C. Claims 7, 8, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie ('781) as applied to claims 1-6, 9-15, 17-25 and 27-31 above, and further in view of either Suthanthiran et al (5,163,896) or Liprie (5,395,300).

As discussed above Liprie ('781) discloses applicant's inventive concept; however, Liprie ('781) does not disclose the rounding of the radioactive core.

Suthanthiran (see abstract and figure 1) teaches the use of rounded titanium encapsulation of radioactive sources in the same field of endeavor for the purpose of effectively sealing radioactive source.

Liprie ('300) further teaches the use of rounded encapsulation of radioactive sources in the same field of endeavor for the purpose of effectively sealing the radioactive source (see figure 1). Additionally note the funnel insertion technique taught in figure 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified source wire of Liprie ('781) to have included encapsulation design teachings of either

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Suthanthiran or Liprie ('300) as such results are in no more than the use of conventionally known radioactive core shapes within the nuclear medicine art.

D. Claims 1-6, 9-15, 17-25 and 27-31 are rejected under 35 U.S.C. 103(a) as obvious over Liprie ('781) in view of Narciso et al (5,454,794) and/or Ishibe et al (5,230,348).

Liprie ('781) as set forth above discloses applicant's inventive concept; however, Liprie ('781) does not disclose the use of a nickel titanium alloy (Nitinol®) as his housing tube or backbone wire material.

Liprie ('781) discloses that the flexible elongated housing tube and backbone wire can be constructed of *stainless steel* or other materials such as *titanium* or *tantalum*.

Stainless steel or *tantalum* are material equivalents for Nitinol® this is evident by Narciso. Referring to column 3, lines 35-40 Narciso teaches that deflecting wires can be fabricated from metals having tensile strength and memory to deflect and return to their original position such as Nitinol®, *stainless steel* or *tantalum*.

Further note that Ni-Ti alloys (i.e., Nitinol®) are well known within the medical guide wire art. This is evident by the teachings of Ishibe wherein a superelastic alloy comprising Ni (50-60% (preferably 54-57%)) and Ti (40-50% (preferably 43-46%)) provides no stress induced martensitic or martensitic reverse transformations in an elongation range of 0-5%.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have replaced the stainless steel or tantalum alloy of Liprie ('781) with the Nitinol alloy teachings of Narciso and/or Ishibe, because such results are in no more than the substitution of conventionally known alloys with little or no memory retention.

(11) Response to Argument

A. The 35 U.S.C. 112, second paragraph, rejection of claims 1-31 is withdrawn.

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B. Claims 1-6, 9-15, 17-25 and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Liprie (5,282,781).

Applicant argues as in Paper no. 19 that the examiner failed to give patentable weight to claim limitations as previously set forth in the Final rejection (Paper no. 20) this is not the case. The response of the Final rejection is provided below.

Applicant argues limitations present in independent claims 1, 13 and 24. In particular applicant asserts that no patentable weight have been given to the claim limitation (present in claims 1, 13 and 24) "housing tube constructed from a material having little or no memory retention when bent." Applicant further argues independent claim 24 citing the limitation "a capsule inserted into said proximal end of the flexible elongated housing."

In regard to applicant's argument that no patentable weight was given to the above limitations the examiner disagrees.

First, with regard to the claim limitation (present in claims 1, 13 and 24) "housing tube constructed from a material having little or no memory retention when bent." Liprie ('781) is inherently capable of meeting applicant's claimed inventive concept. Liprie ('781) discloses *Stainless steel, tantalum and titanium* as housing materials. *Stainless steel* or *tantalum* are material equivalents for Nitinol® this is evident by Narciso et al (5,454,794). Referring to column 3, lines 35-40 Narciso discloses/teaches that deflecting wires can be fabricated from metals having tensile strength and memory to deflect and return to their original position such as Nitinol®, stainless steel or tantalum.

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As to limitations which are considered to be inherent in a reference, note the case law of In re Ludtke, 169 U.S.P.Q. 563; In re Swinehart, 169 U.S.P.Q. 226; In re Fitzgerald, 205 U.S.P.Q. 594; In re Best et al, 195 U.S.P.Q. 430; and In re Brown, 173 U.S.P.Q. 685, 688.

Further note that Ti-Ni or Ni-Ti alloys are well known within the medical guide wire art. This is evident by the teachings of Ishibe et al (5,230,348) which teaches the desired shape memory characteristics of the alloy and the advantages of such when navigating through blood vessels (i.e., navigate tortuous regions).

The use of a secondary reference in connection with a 35 U.S.C. 102 rejection is proper when the secondary reference is cited to show that the primary reference contains an "enabling disclosure". See MPEP § 2131.01.

Second, even if *Stainless steel, tantalum or titanium* as set forth by Liprie ('781) are not considered shape memory alloys (i.e., materials having memory retention to their original shape) the present claim language allows the materials of Liprie ('781) to read on applicant's claimed invention. That is as argued by applicant stainless steel is not a shape memory alloy. Therefore, as claimed housing tube constructed of stainless steel would have little or no memory retention when bent. That is the housing tube would have no memory retention to its original state. That is per applicant's arguments the stainless steel would stay in its bent position. While this is not applicant's claimed intent the claim language allows for this interpretation. Thus, the wording of the claim language is at best poor.

Regarding the second limitation (claim 25) not set forth by Liprie ('781) the examiner again disagrees. As set forth previously Liprie ('781) discloses that it is well known (i.e., conventional) within the art to encapsulate the radiation source in a material such as stainless steel (see column 4, lines 10+) to

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prevent the flaking of the radiation source and to provide such sources with radiopaque markers so as to observe the source with fluoroscopy (see column 16, lines 64+). Applicant argues that the selected passage refers only to the indicated prior art of record for Liprie ('781). The examiner disagrees. Prior art referred to in a reference patent may be used for what it fairly teaches. See In re Fortess and Schoeneberg, 152 USPQ 13. Furthermore, there is no indication within the passage that the referenced prior art refers to only Van't Hooft (4,861,520). The prior art referenced could be referring to the inventor's own personal knowledge.

C. Claims 7, 8, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie ('781) as applied to claims 1-6, 9-15, 17-25 and 27-31 above, and further in view of either Suthanthiran et al (5,163,896) or Liprie (5,395,300).

Applicant's argues that neither Suthanthiran or Liprie ('300) provide for the capsule end to be rounded or the source to be encapsulated. Applicant cites that the use of Suthanthiran with Liprie ('781) is improper as the source of Suthanthiran is directly implanted into the patients body vice applicant's wherein his is utilized within a source wire.

The examiner disagrees. Suthanthiran (column 7, lines 35-50) teaches the sealing or encapsulation of sources to inhibit corrosion from body fluids effecting the source. Liprie ('781)(column 4, lines 10-15) sets forth the encapsulation of prior art sources. Further from figure 1 of Suthanthiran one can clearly see the rounded end of the capsule. While patent drawings are not drawn to scale, relationships clearly shown in the drawings of a reference patent cannot be disregarded in determining the patentability of claims. See In re Mraz, 59 CCPA 866, 455 F.2d 1069, 173 USPQ 25 (1972).

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Therefore, while the source of Suthanthiran is utilized directly in the body the prior art teachings of Liprie ('781) cannot be ignored. Encapsulation was known in the medical radioactive source art. Thus teachings of Suthanthiran are applicable and would have been obvious to one having ordinary skill in the art as such results are in no more than the utilization of conventionally known designs/techniques available within the art.

With regard to applicant's arguments of the combination of Liprie ('781) in combination with Narciso and Liprie ('300) (page 10 of Appeal Brief last paragraph) such is not a rejection set forth by the examiner. Accordingly this argument will not be addressed.

As set forth in the rejection (Liprie ('781) in combination with Liprie ('300)) Liprie ('300) clearly teaches the use of rounded encapsulation of radioactive sources in the same field of endeavor for the purpose of effectively sealing the radioactive source (see figure 1). Thus encapsulation and rounding of the capsule ends are no more than the use of conventionally known designs/techniques available to one having ordinary skill in the art.

D. Claims 1-6, 9-15, 17-25 and 27-31 are rejected under 35 U.S.C. 103(a) as obvious over Liprie ('781) in view of Narciso et al (5,454,794) and/or Ishibe et al (5,230,348).

Here applicant argues that stainless steel, Nitinol and tantalum are not material equivalents as set forth in Narciso.

The examiner has clearly set forth a teaching in the prior art that Stainless steel and tantalum are known equivalents to that of Nitinol as set forth by Narciso. Applicant is questioning the operability/enableness of the reference. When the reference relied upon in the rejection anticipates or makes obvious all the elements of the claimed invention, the reference is presumed to be operable/enabled.

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Once such a reference is found the burden is on the applicant to provide facts to rebut the presumption of operability/enableness. See In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Also see MPEP § 2121. Applicant has had the opportunity to provide experimental evidence (i.e., test results between the exact same source wires constructed of Nitinol, stainless steel and tantalum) to rebut the Narciso reference in not only this case, but the other pending cases 09/455579, 09/445582, etc. and has yet to do so. Accordingly, unless provided the Narciso and Ishibe references have been appropriately applied.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




Jack Keith

December 16, 2003

jwk

Conferees

Michael Carone (SPE, 3641) 

Peter Poon (SPE, 3643)

